STUDY SPONSOR: CBI
STUDY TYPE:
TEST ITEM:
STUDY NUMBER:

INTRODUCTION

The study was performed to assess the acute oral toxicity of the test item following a single oral administration in the Wistar strain rat (General Study Plan 518-12). This study was designed to be compatible with the procedures indicated by the following internationally accepted guidelines and recommendations:

- OECD Guidelines for Testing of Chemicals No 420 "Acute Oral Toxicity - Fixed Dose Method" (2001)
- Method B1 bis Acute Toxicity (Oral) of Commission Regulation (EC) No. 440/2008

Experimental Starting Date: 11 June 2014
Experimental Completion Date: 01 July 2014

Test item characterization data are the responsibility of the Sponsor.

All raw data will be retained in CBI

METHOD

Following a sighting test at a dose level of 2000 mg/kg, an additional four fasted female animals were given a single oral dose of test item at a dose level of 2000 mg/kg body weight. Clinical signs and body weight development were monitored during the study. All animals were subjected to gross necropsy.

RESULTS

Individual clinical observations and mortality data are given in Table 1. Individual body weights and weekly body weight changes are given in Table 2 and individual necropsy findings are given in Table 3.

There were no deaths. No signs of systemic toxicity were noted during the study. All animals showed expected gains in body weight over the study period. No abnormalities were noted at necropsy.

CONCLUSION

The acute oral median lethal dose (LD_{50}) of the test item in the female Wistar strain rat was estimated to be greater than 2000 mg/kg body weight (Globally Harmonized Classification System – Unclassified).

This study was conducted in a facility operating to Good Laboratory Practice within the UK national GLP monitoring programme, but the study report has not been audited by the QA Unit. No formal claim of GLP compliance is made for this study. This report is an accurate record of the study and its outcome.

A. Poob ..... Date: 6/10/14

A Pooles
Study Director

TABLES

Table 1 Individual Clinical Observations and Mortality Data

Dose Level mg/kg	Animal Number and Sex	Effects Noted After Dosing (Hours)				Effects Noted During Period After Dosing (Days)													
		½	1	2	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14
2000	1-0 Female	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2-0 Female	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2-1 Female	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2-2 Female	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2-3 Female	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = No signs of systemic toxicity

Table 2 Individual Body Weights and Body Weight Changes

Dose Level mg/kg	Animal Number and Sex	Body Weight (g) at Day			Body Weight Gain (g) During Week	
		0	7	14	1	2
2000	1-0 Female	166	174	186	8	12
	2-0 Female	164	186	200	22	14
	2-1 Female	161	180	190	19	10
	2-2 Female	166	188	200	22	12
	2-3 Female	177	194	206	17	12

Table 3 Individual Necropsy Findings

Dose Level mg/kg	Animal Number and Sex	Time of Death	Macroscopic Observations
2000	1-0 Female	Killed Day 14	No abnormalities detected
	2-0 Female	Killed Day 14	No abnormalities detected
	2-1 Female	Killed Day 14	No abnormalities detected
	2-2 Female	Killed Day 14	No abnormalities detected
	2-3 Female	Killed Day 14	No abnormalities detected